201-15208B

I U C L I D

Data Set

Existing Chemical	:	ID: 7398-69-8
CAS No.	:	7398-69-8
TSCA Name		2-Propen-1-aminium, *N,N*-dimethyl-*N*-2-propenyl-, chloride
Structural formula	:	CH2=C2H3N.Cl.(CH3)2C2H3=CH2
Molecular formula	:	C8H16N.Cl
Molecular weight	:	161.68

Producer related part

Company	:	DADMAC HPV Challenge Task Group
Creation date	:	27.10.2003

Substance related part

Company	:	DADMAC HPV Challenge Task Group
Creation date	:	27.10.2003

Number of pages	:	
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4

1.0.1 APPLICANT AND COMPANY INFORMATION

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

1.1.1 GENERAL SUBSTANCE INFORMATION

Substance type	:	Organic
Physical status	:	Solid
Purity	:	> 99%.
Remark	:	The commercial product is manufactured and shipped as a solution (60-70%) in water

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

Diallydimethylammonium chloride
27.10.2003

Dimethyldiallylammonium chloride
27.10.2003

N,N-Dimethyl-N-2-propenyl-2-propen-1-aminium chloride
27.10.2003

DADMAC
27.10.2003

DIMDAC
27.10.2003

DMDAAC
27.10.2003

1.3 IMPURITIES

Sodium chloride
28.10.2003

1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

No precautionary label is required
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1.6.2 CLASSIFICATION

NFPA 1; 0; 0
RCRA: not hazardous
DOT: Not regulated
28.10.2003

1.6.3 PACKAGING

1.7 USE PATTERN

Type	:	Industrial
Category	:	Chemical industry; used in synthesis of water soluble polymers, coagulants, retention aids.
Remark	:	Commercial product is manufactured and shipped as a solution in water (60–70%).

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1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

DADMAC is made by reaction of dimethylamine and allyl chloride.
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1.8 REGULATORY MEASURES

None.
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1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

None applicable.
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1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

Listed on all major chemical inventories (TSCA, EINECS, AICS, ECL, etc.)
28.10.2003

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2.1 MELTING POINT

Value	:	=133.02°C.
Method	:	MPBPWIN v1.40.
Year	:	2003.
GLP	:	No.
Test substance	:	DADMAC (100% pure substance).
Reliability	:	(2) valid with restrictions. Generally accepted method of calculation with restrictions.

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2.2 BOILING POINT

Value	:	=370.51°C
Method	:	MPBPWIN v1.40 (adapted Stein & Brown method).
Year	:	2003.
GLP	:	No.
Test substance	:	DADMAC (100% pure substance).
Reliability	:	(2) valid with restrictions. Generally accepted method of calculation with restrictions.

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2.3 DENSITY

Value	:	1.03-1.05
Method	:	Other: No data.
Year	:	No data.
GLP	:	No data.
Test substance	:	DADMAC (70% pure substance).
Reliability	:	(4) not assignable. Only short information available (safety data sheet).

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2.3.1 GRANULOMETRY

Not applicable.
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2.4 VAPOR PRESSURE

Value	:	=3.53 E-6 mm Hg at 25°C
Method	:	MPBPWIN v1.40 (modified Grain method).
Year	:	2003.
GLP	:	No.
Test substance	:	DADMAC (100% pure substance).
Reliability	:	(2) valid with restrictions. Generally accepted method of calculation with restrictions.

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2.5 PARTITION COEFFICIENT

Partition coefficient	:	Octanol-water.
log Pow	:	= -2.49
Method	:	KOWWIN v1.66.
Year	:	2003
GLP	:	No.
Test substance	:	DADMAC (100% pure substance).
Reliability	:	(2) valid with restrictions. Generally accepted method of calculation with restrictions.

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2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	Water.
Value	:	1E6 mg/l at 25°C.
Method	:	WSKOW v1.40.
GLP	:	No.
Test substance	:	DADMAC (pure substance)
Reliability	:	(2) valid with restrictions. Generally accepted method of calculation with restrictions. Additionally, no melting point equation was used

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Solubility in	:	Water.
Value	:	Completely miscible.
Method	:	Other: no data.
GLP	:	No data.
Test substance	:	DADMAC (pure substance)
Reliability	:	(4) not assignable. Only short information available (safety data sheet).

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2.6.2 SURFACE TENSION

2.7 FLASH POINT

Value	:	Does not flash.
Method	:	Other: no data.
GLP	:	No data.
Test substance	:	DADMAC (70% solution in water).
Reliability	:	(4) not assignable. Only short information available (safety data sheet).

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2.8 AUTO FLAMMABILITY

Autoignition Temp.	:	>200°C.
Method	:	Other: no data.
GLP	:	No data.

Test substance : DADMAC (70% solution in water).
Reliability : (4) not assignable.
Only short information available (safety data sheet).

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2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

Value : 100 mPa.s
Method : Other: no data.
GLP : No data.
Test substance : DADMAC (70%).
Reliability : (4) not assignable.
Only short information available (safety data sheet).

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2.14 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

Type	:	Air.
Method	:	AOPWIN v1.90.
Year	:	2003.
GLP	:	No.
Result	:	The atmospheric degradation behavior was assessed using AOPWIN (v. 1.90). An overall OH rate constant of 72.5020 E-12 cm^3/molecule.sec was obtained. The following half-lives can be predicted under the chosen conditions: 0.148 days (12h-day, 1.5 E6 OH/cm^3); 1.770 hours. Overall ozone rate constant = 2.400 E-17 cm^3/molecule-sec. Half-life = 0.477 days (at 7 E11 mol/ cm^3); 11.460 hours.
Test substance	:	DADMAC (pure substance)
Reliability	:	(2) valid with restrictions. Generally accepted method of calculation with restrictions.

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3.1.2 STABILITY IN WATER

Type	:	Abiotic (hydrolysis).
Method	:	HYDROWIN v1.67
Year	:	2003.
GLP	:	No.
Remark	:	Stable (model cannot estimate rate constant for this structure).
Test substance	:	DADMAC (pure substance)
Reliability	:	(2) valid with restrictions. Generally accepted method of calculation with restrictions.

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3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	:	Volatility.
Media	:	Water – air.
Method	:	HENRYWIN v3.10.
Year	:	2003.
Remark	:	The value obtained for Henry's constant was calculated as: Bond contribution method: 7.20 E-12 atm-m^3/mole (group contribution calculation incomplete). According to Thomas (1990), the substance may be considered as "not volatile from water". Henry's LC (VP/WSol estimate using EPI values) = 7.510 E-13 atm-m^3/mole

Test substance : DADMAC (pure substance)
Reliability : (2) valid with restrictions.
Generally accepted method of calculation with restrictions.

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Type : Level III Fugacity Model
Media : Water – air – soil – sediment.
Method : BCFWIN v2.14.
Year : 2003.
Result : The value obtained from the Level III Fugacity Model are as follows:

	Mass Amount (%)	Half-Life (hr)	Emissions (kg/hr)
Air	2.38 E-4	2.7	1000
Water	45.3	360	1000
Soil	54.6	360	1000
Sediment	0.0755	1.44 E3	0

Persistence time = 421 hours.

Conclusion : Regardless of the media to which DADMAC is released, virtually all, at steady state, is in the soil and water phases. Using the default emissions of equal amounts to soil, air, water and sediment (1000 kg/hr for each) the Level III model predicts that the distribution of DADMAC will be 54.6% in soil, 45.3% in water, <0.1% in sediment, and virtually nothing in air.
Test substance : DADMAC (pure substance)
Reliability : (2) valid with restrictions.
Generally accepted method of calculation with restrictions.

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3.3.2 DISTRIBUTION

Media : Air – biota – sediment(s) – soil – water.
Method : Calculation according to Mackay, Level 1.
Year : No data.
Remark : The following parameters were employed in this calculation:

Vapor pressure:	1.8 E-5 Pa	(20°C)	(calculated);
Molecular weight:	207.7 g/mol;		
water solubility:	ca. 6000 g/l	(20°C)	(calculated);
logPow:	–2.55	(25°C)	(calculated).

Result : The following environmental distribution was predicted:
water: ca. 100%; other environmental compartments below 0.001%.
Test substance : DADMAC (pure substance)
Reliability : (2) valid with restrictions.
Generally accepted method of calculation with restrictions.

29.10.2003

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type : Anaerobic soil metabolism
Reference : Reick, 1980a
Soil : Monongahela sandy loam soil

Concentration : DADMAC (75% active; $2X10^6$ DPM (93.3 µCi)
Contact time : 0, 28, 56, 84 days
Degradation : = 0% after 28 day(s)
Year : 1980
Method : Monongahela sandy loam soil was oven-dried and 50 grams/flask used. Flasks were purged with nitrogen and sealed. After 45 days, half were purged again and half were flooded with 5 cc water. C14 radio-labeled DADMAC (75% active; $2X10^6$ DPM (93.3 µCi) was added to each flask. Four replicate flasks from each treatment group were removed after 0, 28, 56 and 84 days. Flasks were extracted with $CaSO_4$ and methanol and the methanol filtered. Radioactivity in the methanol was determined in a liquid scintillation spectrometer. Another aliquot was chromatographed by TLC to determine DADMAC.
Results The results are summarized in the following table:

Days of anaerobic conditions	Non-Extractable Radioactivity (DPMX10^5/50 gm soil)		Extractable Radioactivity (DPMX10^5/50 gm soil)	
	Nitrogen Atmosphere	Flooded	Nitrogen Atmosphere	Flooded
0	5.9	5.9	1.3	1.3
28	6.1	6.1	1.3	1.3
56	6.1	6.2	1.2	1.2
84	6.2	6.2	1.1	1.2

Test substance : 14C-DADMAC (75% active)
Conclusion : DADMAC is not anaerobically degraded
Reliability : (2) valid with restrictions
Acceptable, well documented report which meets basic scientific principles.

29.10.2003 (1)

Type : Anaerobic aquatic metabolism
Reference : Reick, 1980b
Soil : Monongahela sandy loam soil
Concentration : DADMAC (75% active); $2X10^6$ DPM (93.3 µCi)
Contact time : 0, 28, 56 and 84 days
Degradation : 0% after 84 day(s)
Degradation product : Not measured.
Year : 1980
Method : Monongahela sandy loam soil was oven dried and 50 grams/ flask used. Flasks were purged with nitrogen and sealed. After 45 days, half were purged again and half were flooded with 5 cc water. DADMAC (75% active; $2X10^6$ DPM (93.3 µCi) was added to each flask. Four replicate flasks from each treatment group were removed after 0, 28, 56 and 84 days. Flasks were extracted with CaSO4 and methanol and the methanol filtered. Radioactivity in the methanol was determined in a liquid scintillation spectrometer. Another aliquot was chromatographed by TLC to determine DADMAC.
GLP : No
Test substance : 14C-DADMAC (75% active)

Result : The results are summarized in the following table:

Days of anaerobic conditions	Radioactivity (DPMX10^5/50 gm soil)	
	Non-Extractable	Extractable
0	6.0	1.5
1	6.0	1.5
2	6.0	1.5
7	5.9	1.6
14	6.0	1.4
21	6.1	1.5
28	6.1	1.5
56	6.1	1.4
84	6.1	1.2
112	6.1	1.0

Test substance : 14C-DADMAC (75% active)
Conclusion : Dried soil has little impact on DADMAC
Reliability : (2) valid with restrictions
Acceptable, well documented report which meets basic scientific principles.

29.10.2003 (2)

Type : Effects of microbes on metabolism.
Reference : Reick (1980c)
Soil : Monongahela sandy loam soil
Concentration : DADMAC (75% active; $2X10^6$ DPM (93.3 µCi)
Contact time : None
Deg. product : Not measured.
Year : 1980
Method : Monongahela sandy loam soil was used in this study. Soil was placed within 5 cm of the top of each tube and cheesecloth attached to one end to allow drainage. A layer of cheese cloth was place on top of the soil. DADMAC (75% active; $6X10^6$ DPM (280 µCi) was mixed with soil and placed on top of the last cheesecloth layer. Twenty acre inches of water were added to each column and leachate collected. After leaching, the soil was removed from the columns and sectioned into 10 2 cm sections. In the aged columns, the soil was treated uniformly and incubated "aged" for 42 days. This soil was then placed on the cheesecloth and handled as before. Soil was extracted with CaSO4 and methanol and the leachate freeze dried. Both samples were analyzed in a liquid scintillation spectrometer. Flasks were extracted with CaSO4 and methanol and the methanol filtered. Radioactivity in the methanol was determined in a liquid scintillation spectrometer. Another aliquot was chromatographed by TLC to determine DADMAC.
GLP : No
Test substance : 14C-DADMAC

Result : The results are shown in the following table:

Section	Unaged Dpm/gm soil $X10^2$	Aged Dpm/gm soil $X10^2$
1	18.4	36.6
2	35.2	50.0
2	36.7	41.8
4	44.3	36.7
5	31.6	23.5
6	27.3	10.5
7	18.0	10.4
8	5.3	8.2
9	36.4	3.12
10	0.95	0.52

Test substance : 14C-DADMAC (75% active)
Conclusion : DADMAC is more mobile than polyDADMAC
Reliability : (2) valid with restrictions
Acceptable, well documented report which meets basic scientific principles.

29.10.2003 (3)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

Type : Plant availability.
Year : Reick (1980d)
Soil : Monongahela sandy loam soil
Concentration : DADMAC (75% active); $2X10^6$ DPM (93.3 µCi)
Contact time : 0, 2, 4 and 8 weeks
Year : 1980
Method : Monongahela sandy loam soil was used in this study. Both "aged" and unaged soil were used. Soil was placed in a 2 liter glass container suitable for growing plants in a greenhouse. Sediment was applied to soil at the highest level considered to be be a potential use; 22,000,000 dpm/container. Seeds of 4 types of plants, corn, soybeans, carrots and spinach were planted. Plants from each type were removed 2,3,6,and 8 weeks after planting.
GLP : No
Test substance : 14C-DADMAC

Result :

Plant	2 weeks dpm(weight)	4 weeks dpm(weight)	6 weeks dpm(weight)	8 weeks dpm(weight)
UNAGED				
Spinach	678 (0.0186)	1166 (0.0237)	2174 (0.0287)	2176 (0.0266)
Carrot (root)	317 (0.0027)	3233 (030026)	914 (020021)	3267 (0.0225)
Carrot (top)	413 (0.0075)	1076 (0.0181)	1900 (0.0366)	3267 (0.0225)
Soybean (lower)	668 (0.0258)	1220 (0.0181)	2044 (0.0700)	11665 (0.0895)
Soybean (cotyledon)	2966 (0.1046)	2633 (0.0266)		
Soybean (upper)	324 (0.0432)	701 (0.1445)	1236 0.2497)	1206 (0.1925)
Corn	1934 (0.0760)	10716 (0.2112)	17017 (0.4945)	38852 (1.1824)
AGED				
Spinach	367 (0.0176)	568 (0.0145)	618 (0.0203)	1214 (0.0122)
Carrot (root)	239 (0.0043)	2717 (0.0025)	897 (0.0011)	3240 (0.0043)
Carrot (top)	95 (0.0306)	852 (0.0298)	893 (0.0449)	3699 (0.0630)
Soybean (lower)	783 (0.0306)	713 (0.0298)	1424 (0.0449)	1973 (0.0630)
Soybean (cotyledon)	772 (0.0548)	1793 (0.0425)		
Soybean (upper)	192 (0.0420)	291 (0.1296)	654 0.2127)	878 (0.3574)
Corn	1299 (0.0677)	7990 (0.1854)	10572 (0.4188)	27384 (0.9344)

Test substance : 14C-DADMAC (75% active)

Conclusion : Uptake of radioactivity from DADMAC generally increased with time. There was more taken up from unaged than aged soil. In no case, not even corn, did the level approach 0.1%. Essentially no uptake of the 22,000,000 dpm was obtained. The low amount taken up could be due to dust or soil contamination during the greenhouse test.

Reliability : (2) valid with restrictions
Acceptable, well documented report which meets basic scientific principles.

29.10.2003 (4)

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type : Static.
Reference : Johnson, C. (1971).
Species : Blue Gill Sunfish (*Lepomis macrochirus*) (Fish, fresh water).
Exposure period : 72 hours.
Unit : mg/l
LC0 : 56
LC50 : Not observed.
LC50 : Not observed.
Analytical monitoring : No.
Method : Safety Test in Bluegill Sunfish.
Year : 1971
GLP : No.
Test substance : DADMAC (70% solution in water)
Concentrations : 0, 1, 10, 18, 24, 32, 56
Test procedure : Groups of 10 or 20 fresh water Blue Gill Sunfish (*Lepomis macrochirus*) were exposed in a reconstituted medium at 64° - 69°F for 96 hours. The pH was carefully monitored throughout the study. Concentrations of 0.0 (20 fish), 1.0 (10 fish), 10 (10 fish), 18 (10 fish), 24 (20 fish), 32 (20 fish), and 56.0 mg/l (10 fish) of test substance were used. Fish mortality was measured after 24, 48 and 96 hours.
Results : The only toxic sign observed was at 56 mg/l of DADMAC; some of the fish appeared slightly less active than the other fish in the study.

	Mortality			
Test Concentration (mg/L)	24 hours	48 hours	72 hours	96 hours
0	0/20	0/20	0/20	0/20
1	0/10	0/10	0/10	0/10
10	0/10	0/10	0/10	0/10
18	0/10	0/10	0/10	0/10
24	0/20	0/20	0/20	0/20
32	0/20	0/20	0/20	0/20
56	0/10	0/10	0/10	0/10

Since there were no mortalities the LC0 is considered to be 56 mg/l.

Test substance : DADMAC (70% solution in water)
Conclusion : DADMAC has no lethal effects on freshwater fish at concentration up to 56 mg/l. The test substance is not of toxic concern to Blue Gill Sunfish.
Reliability : (2) valid with data
Basic data given: comparable with guidelines/standards

27.10.2003 (5)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : Effect of DADMAC on Daphnids
Exposure period : 48 hour
Unit : mg/l (ppm)

LC50 : $1.57X10^6$
Method : ECOSAR
Reliability : (2) valid with restrictions.
Generally accepted method of calculation with restrictions.

27.10.2003

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Type : Blue-Green Algae Toxicity
Exposure period : 96 hours
Unit : mg/L
LC50 : 33.3
Method : ECOSAR
Reliability : (2) valid with restrictions.
Generally accepted method of calculation with restrictions.

27.10.2003

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type : Effect on soil microbes
Year : Reick (1980e)
Source of Microbes : Monongahela fine sandy loam soil
Exposure period : 3 weeks
Unit : mg/l
LC0 : >10
Analytical monitoring : No
Year : 1980
Method : Moist soil was treated with DADMAC at the rate of 0, 1, 10 ppm. Treatment was replicated three times. Bacterium, actinomycetes, and fungi populations were determined at 0, 1, 2, and 4 weeks after initiation of treatment. One gram of soil was mixed with 99 ml distilled water to enumerate microorganisms. Dilutions were repeated until appropriate concentrations were reached.
GLP : No
Test substance : DADMAC (70% solution in water)
Concentrations : 0, 1 and 10 pp
Results : The only toxic sign observed was at 56 mg/l of DADMAC; some of the fish appeared slightly less active than the other fish in the study.

Test Concentration (mg/L)	Organism	Number (x 10^3)			
		0 weeks	1 week	2 weeks	4 weeks
0	Fungi	23	25	20	28
1		21	26	28	30
10		20	2	24	30
0	Soil Bacteria and Actinomycetes	100	80	75	78
1		100	85	75	80
10		95	90	80	80

No effect from 1 or 10 ppm DADMAC on any population of microbes, bacteria, actinomycetes or fungi was noted

Test substance : DADMAC (70% solution in water)
Conclusion : At the concentrations tested, DADMAC does not affect microbial activity.
Reliability : (2) valid with restrictions
Acceptable, well documented report which meets basic scientific principles.

29.10.2003 (6)

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

Type : Oral absorption, distribution and excretion.
Reference : Easterday, O. (1965a).
Species : Rat.
Strain : Unspecified.
Sex : Male and female.
Number of animals : 3 animals per group.
Vehicle : Water.
Doses : 656 mg/kg (24 hours); 1585 mg/kg (48 hours); 1591 mg/kg (72 hours).
Analytical monitoring : No.
Method : Isotope distribution.
Year : 1975
GLP : No.
Method : Male albino rats were placed in metabolism cages. Following intubation with C14 DADMAC, one animal per time point, urine and feces were collected at 24, 48 and 72 hours. Animals were treated with 656 mg/kg (24 hours); 1585 mg/kg (48 hours) or 1591 mg/kg (72 hours) of C14 DADMAC (100 microcuries/ml: 100 microcuries/1.9 grams. Purity unspecified). Carcasses were frozen and radioactivity determined later in blood, spleen, liver, kidneys, bone marrow, and three sections of gastrointestinal tract. Carcasses, after removal of skin and feet were homogenized and radioactivity determined.
Remark : While this study has marked deficiencies, it demonstrates that DADMAC is poorly absorbed.
Test substance : C14 DADMAC (solution in water)
Result : No change in clinical signs was observed in the treated animals. There was a slight weight loss in the study. The primary route of excretion for C14 derived from DADMAC monomer was feces (see below).

C14 Excretion in:	Treatment (hours)		
	0 to 24 *	24 to 48	48 to 72
Urine	1.3%	0.7%	0.3%
Feces	68%	10%	0.3%
CO_2	0.021%	0.033%	0.012%
*This animal received a slightly reduced dose than the other 2.			

The tissue levels for monomer were very low at each time point and there was no accumulation in any organ. The highest concentration of any organ was liver at 24 hours which had 0.0034% of the administered radioactivity.

Test substance : DADMAC (solution in water)
Conclusion : DADMAC was poorly absorbed. Of the tissues studied, the liver was found to have the largest percent uptake. The principle route of excretion was via the feces followed by the urinary pathway with a very low amount being excreted via the expired air. The largest elimination was observed to occur during the first 24 hours.
Reliability : (2) valid with restrictions.
Acceptable, well documented report which meets basic scientific principles but pre-dates GLP.

29.10.2003 (7)

5.1.1 ACUTE ORAL TOXICITY

Type : Acute oral toxicity.
Reference : Sterner, W (1975)
Value : 3930 mg/kg bw
Species : Rat.
Strain : Wistar
Sex : Male and female.
Number of animals : 40
Vehicle : Water
Doses : 0, 3.18, 3.98, 5.00 and 6.30 ml/kg
Method : Procter and Gamble Standard Procedure 1
Year : 1975
GLP : No
Test substance : DADMAC (64.3% solution in water).
Analytical monitoring : No.
Method : Doses of DADMAC were given by gavage to 3 groups of 10 fasted Wistar rats. Doses were separated by 0.1 log units. Mortality was reported at 1 and 14 days.
Result : Mortality was as follows:

Group	Dose (ml/kg)	1 day mortality	14 day mortality
I	3.18	0/10	0/10
II	3.98	1/10	1/10
III	5.00	6/10	6/10
IV	6.30	10/10	10/10

Test substance : DADMAC
Conclusion : The oral LD50 for the 63% solution was calculated as 4.81 (4.41 - 5.53) ml/kg. The oral LD50 was 3.93 g/kg DADMAC.
Reliability : (2) valid with data
Basic data given: comparable with guidelines/standards

29.10.2003 (8)

Type : Acute oral toxicity.
Reference : Easterday, O. (1965b).
Value : 2520 mg/kg bw
Species : Rat
Strain : Sprague-Dawley
Sex : Male
Number of animals : 30
Vehicle : Water.
Doses : 31.6, 100, 316, 1000, 3160, and 10000 mg/kg.
Method : Not referenced.
Year : 1964
GLP : No
Test substance : White solid.
Analytical monitoring : No.
Method : Groups of 5 fasting male albino Sprague-Dawley rats were treated by gavage with 31.6, 100, 316, 1000, 3160, and 10000 mg/kg representing a spread of 0.3 log units. Rats were observed for 14 days

Result : Mortality was as follows:

Dose mg/kg	Conc. of solution (%)	1 hour	4 hours	24 hours	2 days	3 days	14 days
31.6	1.0	0/5	0/5	0/5	0/5	0/5	0/5
100	1.0	0/5	0/5	0/5	0/5	0/5	0/5
316	10	0/5	0/5	0/5	0/5	0/5	0/5
1,000	10	0/5	0/5	0/5	0/5	0/5	0/5
3,160	40	0/5	0/5	3/5	3/5	3/5	3/5
10,000	40	0/5	1/5	4/5	5/5	5/5	5/5

Test substance : DADMAC.
Conclusion : The acute oral LD50 of DADMAC in rats at 14 days was 2520 (1600 - 4950) mg/kg
Reliability : (2) valid with data
Basic data given: comparable with guidelines/standards

29.10.2003 (9)

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

Type : Primary skin irritation and corrosivity.
Reference : Vinegar, M. (1978).
Species : Rabbit
Strain : New Zealand White
Concentration : Test material as supplied.
Exposure : Back and abdomen, intact and abraded skin; saddle, intact skin
Exposure time : 24 hours (Irritation); 4 hours (Corrosivity).
Number of animals : 6 per test.
Vehicle : None.
PDII (dorsal) : <0.1 (dorsal = 0.09; ventral = 0.04)
Method : Patch Test for Primary Skin Irritation and Corrosivity (Code of Federal Regulations, Title 16, Chapter II, 1976) and Section 173.240 of the department of Transportation Hazardous Materials Regulations (Federal Register, Monday, September 27, 1976).
Year : 1978
GLP : No.
Test substance : CC-47 DADMAC MONOMER
Testing system : Primary Skin Irritation Test (FHSA): 0.5 ml of undiluted test material was applied under a one inch square surgical gauze patch to an intact and abraded skin on both the back and abdomen of 6 New Zealand White rabbits. Each patch was held in place by 2 one inch strips of adhesive tape. After application of the patches, the trunk of each rabbit was wrapped with

rubber dental damming which was secured with staples. After 24 hours, the patches were removed and any residual material was removed. The reactions were scored immediately after the removal of the patches (24-hour reading) and again 48 hours later (72-hour reading). Corrosivity Test (DOT): 0.5 ml of undiluted test material was applied under a one inch square surgical gauze patch to 2 intact areas of skin on each of 6 New Zealand White rabbits. The application sites were prepared by clipping the hair from the saddle areas of the rabbits. Each patch was held in place by 2 one inch strips of adhesive tape. After application of the patches, the trunk of each rabbit was wrapped with rubber dental damming which was secured with staples. The animals were secured in Newmann harnesses for 4 hours. After 4 hours, the patches were removed and any residual material was removed. The reactions were scored immediately after the removal of the patches (4-hour reading) and again at 24 and 48 hours after initial application.

Result : Primary Skin Irritation Test: Following dorsal application, irritative effects noted at the 24-hour reading included very slight erythema at one intact and one abraded site. The Primary Irritation Index (PII) was found to be 0.09. Following ventral application, no irritative effects were noted at the 24-hour reading. However, at the 72-hour reading, very slight erythema was noted at one abraded site. No other irritative effects were noted at any time throughout the study. The Primary Irritation Index (PII) was found to be 0.04. Corrosivity Test: Following patch application, no irritative effects were noted at any time throughout the study

Test substance : DADMAC (solution of unknown concentration).

Conclusion : DADMAC was determined to be not irritating to skin in this assay.

Reliability : (1) valid without restrictions
Guideline study.

28.10.2003 (10)

5.2.2 EYE IRRITATION

Species : Acute eye irritation.

Reference : Vinegar, M. (1978).

Species : Rabbit.

Strain : New Zealand White.

Concentration : Test material as supplied.

Dose : 0.1 ml

Exposure time : 72 hours.

Number of animals : 6

Vehicle : None.

Result : Not irritating

Method : Acute Eye Irritation (Code of Federal Regulations, Title 16, Chapter II, 1976)

Year : 1978

GLP : No.

Test substance : CC-47 DADMAC MONOMER

System of testing : 0.1 ml of the undiluted sample was applied to the right eye of each of 6 New Zealand White rabbits. The left eyes were untreated and served as controls. Examinations for gross signs of eye irritation were made at 24, 48 and 72 hours following application. Scoring of the irritative effects was made according to the method of Draize.

Result : Irritative effects noted at the 24-hour reading following application included slight to moderate conjuctival erythema and slight conjuctival discharge in 3 rabbits. At the 48-hour reading slight to moderate conjuctival erythema was noted in 3 rabbits. At the 72-hour reading slight conjuctival erythema was

noted in 1 rabbit. No corneal opacity or iritis was noted.

Test substance	:	DADMAC (solution of unknown concentration)
Conclusion	:	DADMAC was determined to be not irritating to eyes in this assay.
Reliability	:	(1) valid without restrictions. Guideline study.

28.10.2003 (10)

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Type	:	13-week oral toxicity feeding study.
Reference	:	Tegeris, A. (1976).
Species	:	Dog.
Sex	:	Male & female.
Strain	:	Beagle.
Route of admin.	:	Oral, feed.
Exposure period	:	90 days
Frequency of treatm.	:	Daily.
Post exposure period	:	None.
Doses	:	50, 200, 800 mg/kg/day
Control group	:	Yes, concurrent, no treatment.
NOAEL	:	= 200 mg/kg/day
LOAEL	:	= 800 mg/kg/day
Method	:	13 Week Oral Toxicity Feeding Study in Dogs.
Year	:	1976
GLP	:	No (study was performed to FIFRA guidelines).
Method	:	Groups of 4 male and 4 female purebred beagle dogs, averaging 3 to 4 months old, were fed diets containing 50, 200, or 800 mg/kg/day of DADMAC monomer. Diets were adjusted to deliver specified doses of monomer in a 350 gram meal. The dogs were carefully observed for 13 weeks. Samples were taken for clinical chemistry and hematology at 45 days and at termination. All dogs were necropsied and histopathology performed.
Result	:	At 800 mg/kg/day, there was a decrease in body weight gain. Otherwise there were no treatment related effects in this study. The NOAEL was 200 mg/kg/day.
Test substance	:	DADMAC (45% solution in water).
Conclusion	:	The NOAEL for this study is 200 mg/kg/day.
Reliability	:	(1) valid without restrictions Guideline study.

27.10.2003 (11)

Type	:	13-week oral toxicity feeding study.
Reference	:	Sterner, W. (1976).
Species	:	Rat.
Sex	:	Male & female.
Strain	:	Unspecified.
Route of admin.	:	Oral, feed
Exposure period	:	90 days.
Frequency of treatm.	:	Daily.
Post exposure period	:	None
Doses	:	5, 50, 500 mg/kg/day
Control group	:	Yes, concurrent, no treatment

NOAEL	:	= 50 mg/kg/day
LOAEL	:	= 500 mg/kg/day
Method	:	13-Week Oral Toxicity Feeding Study in Rats
Year	:	1976
GLP	:	No.
Method	:	Groups of 15 male and 15 female rats of unspecified strain were fed diets containing 5, 50 or 500 mg/kg of DADMAC monomer. 5 animals per group were sacrificed at 4, 8 and 13 weeks for histopathology.
Result	:	In the high dose group, a significant decrease in body weight gain was observed. No significant treatment related histopathology was observed in this study. The NOAEL was determined to be 50 mg/kg/day based on body weight gain. A hexibarbitone sleeping time study was included in this study to assess drug metabolizing enzymes. There was no treatment related effect on hexabarbitone sleeping time.
Test substance	:	DADMAC
Conclusion	:	The NOAEL for this study is 50 mg/kg/day.
Reliability	:	(3) not reliable. Insufficient documentation for assessment.

29.10.2003 (12)

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test.
Reference	:	San, R. (1991).
System of testing	:	Salmonella microsome plate test.
Test concentration	:	167, 500, 1670, 5,000, 7,500, and 10,000 µg/plate in the presence/absence of S9.
Cytotoxic conc.	:	No cytotoxicity was observed in this study.
Metabolic activation	:	With and without
Result	:	Negative.
Method	:	As described in Ames (1975) and Maron (1983).
Year	:	1991
GLP	:	Yes.
Method	:	The test compound was evaluated in triplicate cultures in strains TA1535, TA1537, TA1538, TA98 and TA100 in the presence and absence of S9 at the above doses. (Ames *et al*, 1975)
Result	:	The ratio of revertants in treated plates versus controls never exceeded 1.4. No significant increase in mutations either in presence or absence of S-9
Test substance	:	DADMAC (solution in water).
Conclusion	:	Under the experimental conditions, the test substance (DADMAC) did not show mutagenic activity in this bacterial reverse mutation test of *Salmonella typhimurium*.
Reliability	:	(1) valid without restrictions Guideline study.

27.10.2003 (13)

Type	:	Ames test
Reference		De Jouffrey (1996a).
System of testing	:	Salmonella microsome plate test.
Test concentration	:	312.5, 626, 1,250, 2,500 and 5,000 µg/plate in the presence/absence of S9.
Cycotoxic conc.	:	No increase in mutations in presence or absence of S-9.
Metabolic activation	:	With and without.
Result	:	Negative.
Method	:	OECD Guidelines for the Testing of Chemicals, Guideline No. 471, May 1983 (revised September, 1995): "Genetic Toxicology: *Salmonella Typhimurium* Reverse Mutation Assay".

Year : 1996.
GLP : Yes.
Method : The test compound was evaluated in triplicate cultures in strains TA1535, TA1537, TA1538, TA98 and TA100 in the presence and absence of S9 at doses of 312.5, 626, 1,250, 2,500 and 5,000 µg/plate.
Result : Revertant frequencies for all doses of the test compound in all strains with and without S9 approximated or were less than those observed in the concurrent negative control cultures. All positive and negative control values were within acceptable limits.
Test substance : DADMAC (50% solution in water).
Conclusion : Under the experimental conditions, the test substance (DADMAC) did not show mutagenic activity in this bacterial reverse mutation test of *Salmonella typhimurium*.
Reliability : (1) valid without restrictions.
Guideline study.

29.10.2003 (14)

Type : Mammalian cell gene mutation assay.
Reference : De Jouffrey (1996b).
System of testing : Mouse lymphoma ($TK^{+/-}$) L5178Y cells
Test concentration : 625, 1,250, 2,500 and 5000 µg/plate.
Metabolic activation : With and without.
Result : Negative.
Method : OECD Guidelines for the Testing of Chemicals, Number 476, April 4, 1984: "Genetic Toxicology: *In Vitro* Mammalian Cell Gene Mutation Test"
Year : 1996.
GLP : Yes.
Method : Cells were suspended in medium with test article in the presence or absence of S9 metabolic activation for 4 hours. Article was removed by centrifugation and cells washed twice. Cells were plated to determine cell density (cloning efficiency). Cells were selected in the presence of 100 µg/ml TFT after 14 days.
Result : The highest concentration applied produced a decrease of cell culture growth and the cell growth observed at the lowest concentration was approximately in the range of the negative control. No precipitation of test article was observed. No substantial and reproducible increase in mutant colony numbers was observed at any valuated concentration neither in the presence or absence of metabolic activation. Furthermore, there was no indication of a dose-dependant increase in the number of spontaneous mutant colonies in the solvent control. The results of this study are shown below:

Concentration (mg/ml)	S-9	Viability % Survival	Mutant Frequency per 10^6 Survivors
0.00	–	100	53
	+	100	75
0.625	–	105	66
	+	103	62
1.25	–	74	68
	+	103	80
2.50	–	83	63
	+	103	80
5.00	–	89	57
	+	120	54
MMS	–	50	506
CPA	+	61	853

The material did not significantly increase the mutant frequency in this test.

Test substance : DADMAC (50% solution in water)
Conclusion : Under the experimental conditions, the test substance (DADMAC) did not show mutagenic activity in mouse lymphoma cells in the presence or absence of S9 metabolic activation.
Reliability : (1) valid without restrictions.
Guideline study.

28.10.2003 (15)

Type : Cytogenetic assay.
Reference De Jouffrey (1996c)
System of testing : Human lymphocytes.
Test concentration : 1,250,2,500 and 5,000 µg/plate
Metabolic activation : With and without.
Result : Negative.
Method : OECD Guidelines for the Testing of Chemicals, Number 473, May 26, 1983 (revised draft September, 1995): "Genetic Toxicology: *In Vitro* Mammalian Cytogenetic Test".
Year : 1996
GLP : Yes.
Method : Human blood was collected, washed 3 times and suspended at a concentration of $1x10^6$ cells. 5ml-aliquots were incubated at 37°C for 48 hours. Test compound was added to give final concentration of 625, 1250, 2,500 and 5,000 µg/ml (positive and negative controls were used). For metabolic activation 1.25 ml S9 was added to each culture. Cultures were incubated for 24 hours (2 hour exposure). Colchicine was added to each culture. After 2 hours, cells were centrifuged, collected and fixed. Slides were stained using Giemsa solution. Metaphase figures were identified and chromosomes analyzed.
Result : No significant increase in chromosomal damage was seen at any dose tested. No compound-related effect was seen in the presence of metabolic activation.
Test substance : DADMAC (50% solution in water).
Conclusion : Under the experimental conditions, the test substance (DADMAC) was not clastogenic in human lymphocytes.
Reliability : (1) valid without restrictions
Guideline study.

29.10.2003 (16)

5.6 GENETIC TOXICITY 'IN VIVO'

Type : Mammalian cell gene mutation assay.
Reference Putman, D. (1991).
Species : Mice.
Strain : ICR.
System of testing : Bone marrow erythrocytes..
Test concentration : 22, 43 or 85 mg/kg
Control group : Yes, negative and positive
Result : Negative.
Carrier : Water.
Method : A rapid *in vivo* test for chromosomal damage (Heddle, 1973)
Year : 1991
GLP : Yes.

System of testing	:	Male and female ICR mice were exposed to 22, 43 or 85 mg/kg of Diallyldimethylammonium chloride (DADMAC), which was administered at a constant rate of 10 ml/kg as a single IP injection. The high dose level was calculated to be 80% of the LD50. Bone marrow cells, collected at 24, 48 and 72 hours after treatment, were examined microscopically for micronucleated, polychromatic erythrocytes.
Result	:	No change in the ratio of polychromatic erythrocytes to total erythrocytes was observed in the male or female mice in the test article treated groups suggesting the test article did not induce bone marrow toxicity. No significant increase in polynucleated, polychromatic ethrocytes were observed at 24, 48 or 96 hours after dose administration in males or females.
Test substance	:	DADMAC (solution in water)
Conclusion	:	Under the experimental conditions, the test substance (DADMAC) did not increase the incidence of micronuclei in mouse bone marrow.
Reliability	:	(1) valid without restrictions Guideline study.

28.10.2003 (17)

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

Type		Multigeneration reproduction study in rats.
Reference		Adamik, E. (1979).
Species	:	Rat.
Strain		Sprague-Dawley.
Sex	:	Male and female.
Number of animals	:	10 male and 20 female per dose group, 4 dose groups.
Method		National Academy of Sciences Guidelines: Principles and Procedures for Evaluating the Toxicity of Household Substances, Assembly of Life Sciences, National research Council, Prepared for the National Academy of Sciences.
GLP		No.
Year		1979.
Route of admin		Oral; gavage
Test substance		Hompolymer of DADMAC (polyDADMAC), 20% in solution in water containing at least 1% residual DADMAC monomer.
Doses	:	0, 0.375, 12.5 and 125 mg/kg polyDADMAC corresponding to at least 0.00375, 0.125, and 1.25 mg/kg DADMAC.
Vehicle	:	Water.
Control group reatm.	:	1.0 ml/kg deionized water; gavage.
Frequency of treatm.	:	Daily.
Duration of test	:	133 days, F_0 (male & female) = 8 weeks; F_1 = 27 weeks;
Pre-mating exposure		None.
Statistical methods		No statistical analyses were performed. All parameters were within the normal limits for all groups.

Test conditions

Each male was mated with 2 females. F_0 animals (male and female) were treated from day of mating to weaning of the F_1 pups. The F_1 generation was treated from 21 days of age through weaning of the F_{2b} generation. Males were mated with one female until appearance of the copulatory plug. If a plug was not observed within 5 days the female was mated with another male of the same treatment group. At weaning, 10 males and 20 females were randomly selected from each group to later become the F_1 parental generation. When the F_1 animals became sexually mature (40-50 days of age), each male was mated with 2 females of the same treatment group. Selection of mating males and females from the same litter was avoided. If a plug was not noted through 2 estrous cycles (10 days), another male from the same treatment group was placed with the female. When the F_1 generation produced the F_{2a} generation, the litters were weaned at 21 days *post partum* and killed. After an appropriate 15-day rest period, the F_1 generation was mated again. Litters in excess of 10 rats were culled to 10 rats.

The following reproductive parameters were assessed during the study:

Parental generation: Live weight, duration of gestation, evidence of difficult or prolonged labor, maternal neglect and agalactia.

Litters: Total offspring at birth, number and sex of dead at birth, number and sex of abnormal at birth, viable offspring at days 4,7,14 and 21, live weight of litters, viable offspring and sex at birth, 4,7,14 and 21 days.

Gross pathology: Any pup from F_1, F_{2a} or F_{2b} generations appearing abnormal. One normal male and one normal female from each litter was subjected to gross pathology.

Microscopic pathology: Reproductive organs from 10 rats/sex from control and high dose groups were examined.

Other parameters were assessed during the study: Weight gain and clinical signs.

Results

NOAEL for P is 1.25 mg/kg DADMAC (125 mg/kg polyDADMAC).
NOAEL for F_1 is 1.25 mg/kg DADMAC (125 mg/kg polyDADMAC).
NOAEL for F_2 is 1.25 mg/kg DADMAC (125 mg/kg polyDADMAC).

There were no effects on maternal body weights, pup body weights, litter size, mating index, fecundity index, male fertility index, female fertility index, incidence of parturition, live birth and survival indices. The table below summarizes the results.

Dose (mg/kg)*	F_0		F_{1a}		F_{1b}	
	Fertility index	Parturition Index	Fertility index	Parturition Index	Fertility index	Parturition Index
0.00	17/20	100%	17/19	100%	18/19	100%
0.00375	17/20	100%	119/20	100%	18/20	100%
0.125	18/20	100%	18/20	100%	19/20	100%
1.25	16/20	100%	18/19	100%	18/19	100%

* mg/kg DADMAC based on 1% residual monomer in the polyDADMAC product.

There was no compound related on F_{2a} and F_{2b} generation pup body weights. There was also no compound related effects on the number of live births, still births, total litter size, nor any effect on maternal instinct and raising of the pups. There was no compound related mating index, fecundity index, male fertility index, female fertility index, incidence of parturition, live birth and survival indices. No remarkable pathology was noted amongst female F_1 and F_2 animals. Mottled kidneys were found in F_1 but not F_2 males.

Test substance : DADMAC homopolymer (20% solution in water) containing ≥ 1% DADMAC.

Conclusions

The test (polyDADMAC) material produced no increase in the reproductive failure as compared to control group when dosed orally to rats at dose levels of 0.375, 12.5 and 125 mg/kg/day throughout 2 generations. No compound related effect upon fertility index or any other parameters evaluated was observed. Based on a minimum residual DADMAC monomer concentration of 1% by weight, the No Observed Adverse Effect Level (NOAEL) for DADMAC is 1.25 mg/kg/day.

Reliability

(1) valid without restrictions.
Guideline study.

29.10.2003 (18)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Type Rat teratology study.
Reference Palmer, K. (1991).
Species : Rat.
Sex : Female
Strain : Sprague-Dawley.
Number of animals : 24 per dose group, 5 dose groups.
Method National Academy of Sciences Guidelines: Principles and Procedures for Evaluating the Toxicity of Household Substances, Assembly of Life Sciences, National research Council, Prepared for the National Academy of Sciences.
Route of admin. : Oral, gavage.
Test substance Hompolymer of DADMAC (polyDADMAC), 30% in solution in water

		containing at least 1% residual DADMAC monomer.
Doses	:	50, 150, 450 and 600 mg/kg polyDADMAC corresponding to at least 0.5, 1.5, 4.5 and 6 mg/kg DADMAC.
Exposure period	:	Gestational days 6 to 15.
Frequency of treatm.	:	Daily.
Duration of test	:	Gestational Days 0 to 20.
Control group	:	Yes, concurrent vehicle.
NOAEL maternal tox.	:	= 6 mg DADMAC/kg bw (600 mg polyDADMAC/kg bw).
NOAEL Embryotoxicity	:	= 6 mg DADMAC/kg bw (600 mg polyDADMAC/kg bw).
NOAEL Fetotoxicity	:	= 6 mg DADMAC/kg bw (600 mg polyDADMAC/kg bw).
GLP	:	Yes.
Year	:	1991
Method	:	PolyDADMAC was administered by gavage once daily on gestational days (gd) 6-15, at doses of 50, 150, 450 and 600 mg/kg (corresponding to doses of 0.5, 1.5, 4.5 and 6.0 mg/kg DADMAC). There were 24 time-mated females per group. Clinical observations were made daily except during the dosing period where they were made twice daily. Maternal body weights were monitored and food consumption was measured. At scheduled sacrifice on gd 20, the dams were evaluated for gravid uterus weight, numbers of *corpora lutea*, and live and dead fetuses were determined. Fetuses were analyzed for skeletal anomalies and malformations.
Result	:	There was no compound related effect on body weight or body weight gain. Food consumption was significantly suppressed on days 6 through 11. Otherwise, all measured maternal parameters were normal. With regard to fetuses, their weight and sex were similar to control and no compound related malformations or anomalies observed.
Test substance	:	DADMAC homopolymer (30% solution in water) containing ≥ 1% DADMAC.
Conclusion	:	The No Adverse Effect Level (NOAEL) of polyDADMAC in this study was the highest dose tested, *i.e.*, 600 mg/kg/day. Based on a residual concentration of 1% DADMAC in the test material, the NOAEL for DADMAC for embryonic development is 6 mg/kg/day.
Reliability	:	(1) valid without restrictions Guideline study.

27.10.2003 (19)

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

Avoid all contact with the product by ingestion, inhalation or contact with the skin, eyes and clothing. Do not breathe vapors or spray mist. Wash hands and face before breaks and immediately after handling the product. When using, do not smoke. Handle in accordance with good industrial hygiene and safety practice.
Store in contact with air. Do not exceed storage temperature of 30°C. Protect from light.
28.10.2003

8.2 FIRE GUIDANCE

This product does not burn in aqueous solution. No special precautions are required. In case of fire, wear a self contained breathing apparatus. Keep containers cool during fire with water spray.
28.10.2003

8.3 EMERGENCY MEASURES

If product is inhaled, move to fresh air.
In case of skin contact, rinse and wash contaminated clothing before re-use. Wash contaminated area immediately for at least 15 minutes. In case of persistent skin irritation, consult a physician.
In case of eye contact, rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing and lift upper and lower ids to ensure complete removal of chemical. In case of persistent eye irritation, consult a physician.
If swallowed, do not induce vomiting. Rinse mouth (never give anything by mouth to an unconscious person). Call a physician immediately.
In case of accidental release, do not allow product to enter drains. Do not contaminate water. Dam up spills. Soak with inert absorbent material. If liquid has been spilled in large quantities, clean up promptly by scoop or vacuum. Keep in suitable and closed containers for disposal. After cleaning, flush area with water.
28.10.2003

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

Not applicable.
28.10.2003

8.5 WASTE MANAGEMENT

Can be land filled or incinerated when in compliance with local regulations.
28.10.2003

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

(1) Rieck, C.E. (1980a). Anaerobic Soil Metabolism of DMDAAC and Catfloc T. University of Kentucky, Lexington, KY.

(2) Rieck, C.E. (1980b). Anaerobic Aquatic Metabolism of DMDAAC and Catfloc T. University of Kentucky, Lexington, KY.

(3) Rieck, C.E. (1980c). Effects of Microbes on the Metabolism of DMDAAC and Catfloc T. University of Kentucky, Lexington, KY.

(4) Rieck, C.E. (1980d). Plant Availability of DMDAAC and Catfloc T. University of Kentucky, Lexington, KY.

(5) Johnson, C.D. (1971). DMDAAC - Safety Test in Blue Gill Sunfish. Woodard Research Corp., Herndon, VA.

(6) Rieck, C.E. (1980e). Effects of Catfloc T and DMDAAC on Soil Microorganisms University of Kentucky, Lexington, KY.

(7) Easterday, O.D. (1965a) Oral Absorption, Distribution and Metabolism of 14C-Diallyldimethylammonium Chloride Monomer and Polymer. Hazleton Laboratories, Falls Church, VA.

(8) Sterner, W. (1975) Acute Oral Toxicity in Rats. International Bioresearch Laboratories, Hanover, Germany.

(9) Easterday, O.D. (1965b) Acute Oral Absorption – Rats , Diallyldimethylammonium Chloride Polymer and Diallyldimethylammonium Chloride Monomer. Hazleton Laboratories, Falls Church, VA.

(10) Vinegar, M.B. (1978). Primary Skin Irritation (FHSA), Corrosivity (DOT), and Acute Eye Irritation (FHSA) Studies of CC-47 DMDAAC Monomer. Hilltop Laboratories, Miamiville, OH.

(11) Tegeris, A. (1976). DADM: Ninety Day Feeding to Dogs. Pharmacopathics Reserach Laboratories, Laurel, MD.

(12) Sterner, W. (1976). 13 Weeks Oral Toxicity Feeding Study with Monomer in Rats. International Bioresearch Laboratories, Hanover, Germany.

(13) San, R. (1991). Salmonella/Mammalian - Microsome Plate Incorporation Mutagenicity Assay (AMES TEST). Microbiological Associates, Rockville, MD.

(14) de Jouffrey, S. (1996a). Bacterial Reverse Mutation Test - Diallyldimethylammonium chloride. Centre International de Toxicologie (CIT), Miserey, France.

(15) de Jouffrey, S. (1996b). *In vitro* Mammalian Cell Gene Mutation Test L5178Y TK+/- Mouse Lymphoma - Diallyldimethylammonium chloride. Centre International de Toxicologie (CIT), Miserey, France.

(16) de Jouffrey, S. (1996c). *In vitro* Mammalian Chromosome Aberration Test in Cultured Human Lymphocytes - Dimethyldiallylammonium chloride. Centre International de Toxicologie (CIT), Miserey, France.

(17) Putnam, D. (1991). Micronucleus Cytogenetic Assay in Mice. Microbiological Associates, Bethesda, MD

(18) Adamik, E. (1979). Segment I Multigeneration Study in Rats with Cat Floc T. Wil Research Laboratories, Cincinnati, OH.

(19) Palmer, K. (1991). Poly (dimethyl diallyl ammonium chloride) (PDADMAC) - Oral (Gavage) Rat Teratology Study. Toxicol Laboratories, Ltd., Ledbury, UK.

10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT